PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Edward J. Koeneman	Examiner:	Jonathan M. Foreman
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Title: SYSTEM AND METHOD FOR NEUROMUSCULAR REEDUCATION

CERTIFICATE OF TRANSMISSION

I hereby certify that this document is being transmitted electronically to the United States Patent and Trademark Office via the EFS Web e-Filing system on December 7, 2009.

Name: Shaula Stephenson

DECLARATION OF ALL INVENTORS EDWARD J. KOENEMAN, JAMES B. KOENEMAN, DONALD E. HERRING AND ROBERT S. SCHULTZ PURSUANT TO 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Edward J. Koeneman, Ph.D., having my business address at Kinetic Muscles, Inc., 2103 E. Cedar Street, Suite 3, Tempe, AZ 85281, hereby declare:

I, James B. Koeneman, Ph.D., having my business address at Kinetic Muscles, Inc., 2103 E. Cedar Street, Suite 3, Tempe, AZ 85281, hereby declare:

I, Donald E. Herring, having an address at 4041 North 14th Place, Phoenix, AZ 85014, hereby declare:

I, Robert S. Schultz, having an address at 3229 Cotton Plant Road, Memphis, TN 38119, hereby declare:

1. We, Edward J. Koeneman, Ph.D., James B. Koeneman, Ph.D., Donald E. Herring and Robert S. Schultz, are joint inventors of the subject matter claimed in the above-cited patent application entitled "SYSTEM AND METHOD FOR NEUROMUSCULAR REEDUCATION." Kinetic Muscles, Inc. is the assignee of this patent application. We often refer to this invention as the "air muscle."

2. We are familiar with the above-cited application. We are also familiar with the Office Actions mailed April 1, 2009 and November 20, 2009. We are aware that the Examiner has rejected the claims under 35 U.S.C. §102 and §103 as being obvious over McBean et al. (US 7,396,337) in view of Meyer (US 5,012,820), Grove et al. (US 6,010,468), and Wood et al. (US 2002/0143277). The Examiner states that the McBean et al. reference discloses an orthotic device that detects signals from various EMG and joint position sensors on a patient's limb or body part and causes the patient's joint to move accordingly. We disagree with the Examiner's analysis of the references and conclusions. However, the McBean et al. reference is not applicable to our patent application, and we will discuss that issue below.

BACKGROUND

3. Our claimed invention, which is a system for assisting neuromuscular function that includes an EMG sensor, joint position sensor, computer processor for implementing a protocol, and motion causing device, was conceived and diligently reduced to practice prior to the earliest claimed priority date of November 21, 2002 of the McBean et al. reference. Since well before that date, we have been diligently testing, experimenting and perfecting the invention, which was actually reduced to practice prior to November 21, 2002, as discussed in the next paragraph.

4. As proof of these facts, on March 29, 2001, we submitted a confidential Small Business Innovation Research Program (SBIR) Phase I contract proposal "Development of a Massed Practice Stroke Therapy Device" to the National Institutes of Health (NIH). Exhibit A. The SBIR Phase I contract proposal confirms that we had conceived the key aspects of our invention as relevant to the McBean et al. reference well before November 21, 2002. For

example, on page 14, the document illustrates that we had conceived a lightweight air muscle actuated device that incorporates EMG sensing, neuromuscular stimulation and joint position sensing. Furthermore, on page 15, the document describes a protocol where, if an EMG signal is present but no motion from the patient occurs, the air muscle is stimulated and the joint is moved. If motion is also detected, the air muscle is triggered when the motion has stopped. On page 12 of Exhibit A, we note that "[w]e have constructed a laboratory-based prototype..." prior to the date of the SBIR submission on March 29, 2001.

5. The NIH posed questions regarding our SBIR Phase I contract proposal, to which we responded with a revised SBIR Phase I proposal that was submitted to the NIH on November 30, 2001. A copy of the revised SBIR Phase I proposal is attached as Exhibit B.

6. The NIH posed further questions to which we responded with a second revised SBIR Phase I proposal submitted to the NIH on July 29, 2002. A copy of the second revision of the SBIR Phase I proposal is attached as Exhibit C.

7. We eventually obtained NIH funding in excess of $5 million for our company and for our clinical partners for development and testing of three devices covered by the pending application, for treatment of hand, foot and upper extremity conditions.

GENERAL DISCUSSION OF THE ISSUES

8. In his office action dated November 20, 2009, the Examiner stated on page 5, in the last sentence of paragraph 7, that "the declaration fails to point out where at least one force sensor for measuring a parameter indicative of muscle resistance, where a valve, and where a first and second display have been conceived." The device that we had conceived prior to March 29, 2001 did, in fact, include each and every one of these features. We will specifically point to these features as they are discussed in the supporting exhibits. We will also go through each pending claim to show where the claim elements are discussed in the documents that predate the effective date of the McBean reference.

9. Specifically with respect to claims 69 and 71-80, our device was a system for assisting neuromuscular function and included an EMG sensor for detecting self-actuation of a neuromuscular system, a joint position sensor for detecting self-actuation of a joint, a force sensor for measuring a parameter indicative of muscle resistance, a computer processor for implementing a protocol responsive when self-actuation or attempted self-actuation was detected by the EMG sensor but was not detected by the joint position sensor and a motion causing device for assisting the joint in movement, the motion causing device following the protocol implemented by the computer processor. This device also included an electronic memory system for storing information regarding the patient. The protocol was based on previous measurements recorded from the EMG sensor, joint position sensor and force sensor. This device, which predated March 29, 2001, also included a neuromuscular electrical stimulating (NMES) system for providing neuromuscular stimulation to the neuromuscular system.

10. Our device had an air-muscle as described in the specification, which was the motion causing device mentioned above. The air muscle included a port for supplying pressurized air to inflate the air muscle. The computer processor controlled the valve that controlled the supply of pressurized air to the air muscle.

11. This same device included a first display for depicting the electrical activity from the EMG sensor, and a second display indicating the degree of flexor resistance torque measured by the force sensor. The displays provided a means for the patient to monitor the compliance and performance. The controller updated the displays in a predetermined manner to provide a mechanism for the patient to improve performance and compliance.

12. The pre-March 29, 2001 device had all of the elements of claims 82 and 83. It was a system for assisting neuromuscular function and had a joint position sensor for detecting self-actuation of a joint and measuring a joint motion; a computer processor for implementing a protocol responsive when self-actuation was detected by the joint position sensor and the measured joint motion had not achieved a predetermined value, or when self-actuation was attempted and the measured joint motion had not achieved a predetermined value. The device had a motion causing device for assisting the joint in movement, with the motion causing device

following the protocol implemented by the computer processor such that the joint motion achieved the predetermined value. The motion causing device was an air muscle.

DISCUSSION OF THE CLAIM ELEMENTS

13. Attached to this Declaration as Exhibit D is a copy of the claims that are presently pending. All of the structural elements included in these claims were present in the air muscle that we conceived prior to March 29, 2001. Each claim element will be discussed below, in the order appearing in the claims. Not all references in the SBIR documents relating to each claim element will be cited. We will cite enough references to make the point, but other references to the structure might be found in other places in the documents.

14. The preambles for all the claims state that they claim "a system for assisting neuromuscular function." In Exhibit A, at page 2 thereof, we state that "[t]he long-term objective is to provide a lightweight device for home use that provides motion, biofeedback, and neuromuscular stimulation." We clearly conceived and reduced to practice a device as described in the preambles prior to the effective date of the McBean reference.

15. The first element in claim 69 states "at least one EMG sensor for detecting self-actuation of a neuromuscular system". This is discussed in Exhibit A at pages 12 and 16. A number of features in the claims are discussed on page 12, and a paragraph from that page is quoted below for convenience. We will refer to it and the underlined phrases throughout this declaration.

> The labor-intensive and long treatment times of massed practice make effective rehabilitation expensive. A promising approach to providing a lightweight, low-cost stroke therapy device is a system that synergistically combines three modes of treatment that individually have been shown to be effective (massed practice, electrical neuromuscular stimulation, and biofeedback). We have constructed a laboratory-based prototype of an air muscle powered therapy device that has the adaptability to be used in current treatment modalities and also in the refinement of rehabilitation methods. We attached an artificial muscle between the proximal forearm and a hook on the proximal dorsal region of the hand. A data acquisition board (Data Translation) and software (LabTech Notebook) were used with a Pentium computer to control an air valve to the muscle and record wrist extensor

> EMG and wrist position. Images Company, Staten Island, NY, supplied the wrist position sensor. The air tank supplying the muscle was kept at pressure by a compressor. The PC-based system is useful for the development of control and recording strategies. The EMG sensor feeds back information to the patient to reinforce when wrist extensors are active. The EMG signal can also be used to trigger passive motion using the artificial muscle and to provide neuromuscular stimulation. The purpose of this proposal is to transform this PC-based prototype into a self-contained patient wearable device that records and later displays patient performance. (emphasis added)

The EMG sensor is clearly called out in the above paragraph. Page 16 of Exhibit A shows Figures 1 and 2. An EMG Sensor is clearly shown in Figure 1.

16. The next element in claim 69 states "at least one joint position sensor for detecting self-actuation of a joint." This is discussed in Exhibit A at page 12 in the same paragraph quoted above. The "joint position sensor" is the "wrist position sensor" discussed in that paragraph. It is also shown at page 16 in Figure 1 as a Joint Position Sensor.

17. The next element in claim 69 states "at least one force sensor for measuring a parameter indicative of muscle resistance." This feature was present in the device that existed at the time the Exhibit A submission was made, and is inherent to the operation of the device as discussed in Exhibit A beginning at the last paragraph on page 11 and continuing through the second paragraph on page 12. The air muscle generates a certain force depending on the resistance provided by the antagonist human muscle. The air muscle can be calibrated to display the human muscle resistive force. Alternatively, force sensors can be used to measure the human muscle resistive force. In the second SBIR submission, Exhibit B, submitted prior to the effective date of McBean, specifically states on page 17, at numbered item 2, that the device will "[m]easure the patient physiological changes of active range of wrist extension, EMG extensor activity, and flexor force resistance to motion during the course of therapy." Force resistance is measured by a force sensor. Furthermore, page 19 of Exhibit B states "Resistance to extension is measured by force sensitive resistors (FSRs) placed on the driving bar. This is a measure of the combined wrist and finger flexor muscle resistance." Also, Exhibit B, page 22 shows a flow chart of the functionality of the device. A "Hand Force Sensor" is shown near the upper part of

the middle third of the diagram. Clearly, this shows that our early devices included "at least one force sensor."

18. The next element in claim 69 states "a computer processor for implementing a protocol responsive when self-actuation or attempted self-actuation is detected by the at least one EMG sensor but is not detected by the at least one joint position sensor." We again refer to Exhibit A, page 12 which discusses a "Pentium computer to control an air valve to the muscle and record wrist extensor EMG and wrist position." Also, a microprocessor is shown in Exhibit A at page 16, Figure 1." Clearly, this element was included in our early device.

19. The next element in claim 69 states "a motion causing device for assisting the at least one joint in movement..." This feature is discussed in several places as the "artificial muscle" or "air muscle," including in Exhibit A beginning at the last paragraph of page 11 and extending to page 12. It is also discussed in the second paragraph on page 12, quoted above. It is also depicted on page 16 of Exhibit A in Figures 1 and 2.

20. The next pending claim is 71, which calls out "an electronic memory system for storing information regarding the patient." This can be the Pentium computer discussed above in the quote from Exhibit A at page 12 thereof.

21. The next pending claim is 72, which calls out "wherein the protocol is based on previous measurements recorded from at least one of the EMG sensor, joint position sensor, and force sensor." In Exhibit A, page 15, the last sentence of the second paragraph states that the "clinician will be provided with basic sequences and triggering modes to choose from and also given the ability to custom design a treatment sequence." In this embodiment, the clinician bases the protocol on the prior measurements from at least one of the sensors. Also, at page 12 of Exhibit A (highlighted above), and in other places, we discuss the concept of "massed practice." Typically, to someone ordinarily skilled in the art, that discussion denotes that protocols are changed based on the patient's performance as measured by various sensors.

22. The next pending claim is 73, which calls for "at least one neuromuscular electrical stimulating (NMES) system for providing neuromuscular stimulation..." This is

discussed in several places in Exhibit A including in the first paragraph on page 10 ("neuromuscular stimulation"), page 12 (see highlighted phrase above) and page 16, Figure 1 (Neuromuscular Stimulator.)

23. The next pending claim is 74 which states that "the motion causing device is an air muscle. This was discussed previously, and is found in Exhibit A at pages 11-12, page 12 (highlighted above) and on page 16 in Figures 1 and 2.

24. The next pending claim is 75 which states "wherein the air muscle includes at least one port for supplying pressurized air to inflate said air muscle." The discussion at page 12 of Exhibit A, highlighted above, discusses an air tank supplying the air muscle and an air valve. Figure 1 on page 16 shows a hose to an air supply. Clearly, there is a port through which air flows to the air muscle.

25. The next pending claim is 76 which states that "the computer processor controls at least one valve." Highlighted above in the paragraph from page 12 of Exhibit A is the phrase "Pentium computer to control an air valve." Clearly, this feature was conceived prior to the date of Exhibit A.

26. The next pending claims are 77 and 78, which include, respectively, a first display for depicting the electrical activity from the EMG sensor and a second display to depict a degree of flexor resistance torque measured by the at least one force sensor. Two different displays are clearly discussed in Exhibit A. Either can be called the first or the second display. One display is an LCD display that is shown on the bicep portion of the device in the drawings on page 16 of Exhibit A. The other display is a Pentium computer which is discussed in Exhibit A at page 12. It was a typical laptop computer with a display. Additionally, Exhibit B includes a flow diagram at page 22 that shows, in the left portion near the top, an LCD Display and EMG Biofeedback LEDs. These are first and second displays that depict the electrical activity from the EMG sensor and output of a force sensor, among other things. The flow chart shows the many functions and measurements that are made and then displayed on the two displays. They include a Hand Force Sensor, Angular Position Sensor, Muscle Pressure Sensor and EMG Sensor, plus

control functions such as Valve Open/Close Control, Digital Inputs, Microprocessor, Analog Signal Conditioning and Digital Outputs to the two displays.

27. The next pending claim is 79, which states that the "displays provide a means for the patient to monitor the compliance and performance." We refer to Exhibit A, page 12 quoted above, and page 15 in the first line wherein a "local display" is discussed. Additionally, the figures on page 16 show a display that the patient may monitor for compliance and performance. We also refer to the flow diagram on page 22 of Exhibit B which shows the Visual Biofeedback LED Array and Digital Outputs to the LCD Display. The Digital Outputs may be various depictions of the data read from the various sensors and processed by the Microprocessor.

28. The next pending claim is 80, wherein "the controller updates the displays in a predetermined manner to provide a mechanism for the patient to improve..." We refer to Exhibit A, page 12 quoted above, and Exhibit B, page 22 which shows a microprocessor as the controller and updater of both displays. Exhibit B beginning at the last paragraph of page 23 and extending to page 24 discusses this functionality and ends with the comment "[t]hus joint position serves as the basis for subsequent training each day." These references clearly show that our early device had the requisite elements "to provide a mechanism for the patient to improve."

29. The next pending claim is 82, which includes many of the items discussed above, so they will not be repeated here. With respect to the discussion of the computer processor implementing the protocol, we refer to Exhibit A, page 15, second paragraph, which describes implementation of protocols relating to the same measurements as mentioned in the claim. These protocols are also discussed in Exhibit A in the paragraph beginning on page 11 and extending to page 12.

30. The last pending claim is 83, which states that the motion causing device is an air muscle. This point has been amply discussed above.

31. Nothing in the above discussion of the claims should be interpreted as limiting the interpretation of the claims in any way. The purpose of the discussion was to demonstrate that our early device, which predated the McBean reference by a significant period of time, was fully

conceived and was reduced to practice with proper diligence. The claims are intended to be read as broadly as legally possible, and are not limited in any way by the structure of our early device or our early discussion of the device.

THE REJECTIONS

32. The device discussed in the Exhibit A document included all of the elements claimed in the subject patent application, including the features called out by the Examiner in his Office Actions dated April 1, 2009 and November 20, 2009.

a. The Examiner stated in his office actions:

> In regard to claims 69, 71, 72, 74 and 75, McBean et al. disclose a system for assisting neuromuscular function comprising: at least one EMG sensor (54a) for detecting self-actuation of a neuromuscular system; at least one joint position sensor (54b) for detecting self-actuation of a joint; at least one force sensor for measuring a parameter indicative of muscle resistance (Col. 6, lines 33-50; Col. 9, lines 8-10); a computer processor (Col. 7, lines 4-5) for implementing a protocol responsive when self-actuation or attempted self-actuation is detected by the at least one EMG sensor but is not detected by the at least one joint position sensor (Col. 7, lines 12-17; Col. 8, lines 1-21); and a motion causing device for assisting the at least one joint in movement, said motion causing device following the protocol implemented by the computer processor (Col. 8, lines 5-8). The system includes an electronic memory for storing information regarding the patient (Col. 10, lines 13-15). The protocol is based on previous measurements recorded from the EMG sensor, joint position sensor or the force sensor (Col. 10, lines 13-15). The motion causing device is an air muscle that includes at least one port (Col. 8, lines 43-45).

Our device, as it was conceived prior to March 29, 2001 as discussed above, included each and every one of these features alleged by the Examiner to be disclosed in the McBean reference. Our device was a system for assisting neuromuscular function comprising: at least one EMG sensor for detecting self-actuation of a neuromuscular system; at least one joint position sensor for detecting self-actuation of a joint; at least one force sensor for measuring a parameter indicative of muscle resistance; a computer processor for implementing a protocol responsive when self-actuation or attempted self-actuation was detected by the at least one EMG sensor but was not detected by the at least one joint position sensor; and a motion causing device

for assisting the at least one joint in movement, said motion causing device following the protocol implemented by the computer processor. Our system dating back prior to March 29, 2001 included an electronic memory for storing information regarding the patient. The protocol was based on previous measurements recorded from the EMG sensor, joint position sensor or the force sensor. Our motion causing device was an air muscle that included at least one port.

b. The Examiner further stated in his office actions:

> In regard to claims 82 and 83, McBean et al. disclose a system for assisting neuromuscular function comprising: at least one joint position sensor (24) for detecting self-actuation of a joint and measuring a joint motion (Col. 7, lines 33-48); a computer processor (34) for implementing a protocol responsive when self-actuation is detected by the at least one joint position sensor and the measured joint motion has not achieved a predetermined value or when self-actuation is attempted and the measured joint motion has not achieved a predetermined value (Col. 7, lines 12-17; Col. 8, lines 1-21; Col. 9, lines 8-10); and a motion causing device for assisting the at least one joint in movement, said motion causing device following the protocol implemented by the computer processor such that the joint motion achieves the predetermined value (Col. 8, lines 5-8). The motion causing device is an air-muscle (Col. 8, lines 43-45).

Our device, as it was conceived prior to March 29, 2001 as discussed above, included each and every one of these features alleged by the Examiner to be disclosed in the McBean reference. Our device was a system for assisting neuromuscular function comprising: at least one joint position sensor for detecting self-actuation of a joint and measuring a joint motion; a computer processor for implementing a protocol responsive when self-actuation was detected by the at least one joint position sensor and the measured joint motion had not achieved a predetermined value or when self-actuation was attempted and the measured joint motion had not achieved a predetermined value; and a motion causing device for assisting the at least one joint in movement, said motion causing device following the protocol implemented by the computer processor such that the joint motion achieved the predetermined value. The motion causing device was an air muscle.

CONCLUSION

33. The referenced documents dated March 29, 2001 (Exhibit A), November 30, 2001 (Exhibit B) and July 29, 2002 (Exhibit C) demonstrate that work on this project continued diligently since before the effective date of the McBean et al. reference. Our provisional patent application was filed on December 4, 2002.

34. Throughout this entire period, we continued to actively work on this project, including conducting a pilot study between about August 2002 through November 2002 to gather performance data. During the study, we measured performance of the device and protocols, asked the participants to fill out questionnaires, conducted focus groups, etc. As a result of the study, we made changes to the device and protocols. However, all of the features the Examiner cited as being included in the McBean reference were present in our device since prior to March 29, 2001.

35. We also conducted tests on stroke patients with our device during this period, and eventually obtained FDA registration in 2003. We had begun our discussions with the FDA in early 2001. Clinical testing began in August 2002. The device that is the subject of the pending patent application, which we now call the Hand Mentor, was classified as a "Non Significant Risk" and, therefore, we did not need an Investigational Device Exemption (IDE) for testing of this device. We also received notification from the FDA that our device did not require a 510(K) application. We received our registration number from the FDA on May 28, 2003 (FDA registration no. 9056585).

36. In summary, we began development of our invention well before the effective date of the McBean et al. reference, and continued working diligently on its development up until we filed our provisional patent application on December 4, 2002 and our non-provisional patent application on December 2, 2003. By March 29, 2001, prior to the effective date of McBean et al., we had developed all of the major components of our invention as claimed in our pending patent application, and including the features cited by the Examiner as being disclosed by McBean.

37. We each make our oaths below.

I, Edward J. Koeneman, Ph.D. further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Edward J. Koeneman

Edward J. Koeneman, Ph.D.

12/03/09

Date

I, James B. Koeneman, Ph.D. further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

James B Koeneman

James B. Koeneman, Ph.D.

12/03/2009

Date

I, Donald E. Herring further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Donald E. Herring

12/06/'09
Date

I, Robert S. Schultz further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Robert S. Schultz

Date

I, Donald E. Herring further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

_____
Donald E. Herring

_____
Date

I, Robert S. Schultz further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Robert S. Schultz
Robert S. Schultz

12.04.09
Date